510(k) Summary of Safety and Effectiveness

MAY - 3 2012

SUBMITTER:	Covidien 60 Middletown Avenue North Haven, CT 06473 Tel. No.: (203) 492-5496 Fax No.: (203) 492-5029
CONTACT PERSON:	Angela Van Arsdale Regulatory Affairs Product Specialist
DATE PREPARED:	April 02, 2012
TRADE/PROPRIETARY NAME:	ENDO CLIP™ III 5mm Clip Applier
COMMON/USUAL NAME:	Implantable Clip
CLASSIFICATION NAME:	Implantable Clip
PREDICATE DEVICE(S):	ENDO CLIP™ III 5mm Clip Applier (K071406)
DEVICE DESCRIPTION:	The ENDO CLIP™ III 5mm Clip Applier contains 16 titanium clips. The applier is designed for introduction and use through an appropriately sized trocar sleeve, or larger with the use of a converter. The ENDO CLIP™ III 5mm Clip Applier consists of a trigger handle, shaft rotation knob, clip counter window and a 33 cm shaft with jaws at its distal end. Squeezing the handle places a titanium clip in the jaws and closes the jaws to close the clip on the vessel or structure.
INTENDED USE:	The ENDO CLIP™ III 5mm Clip Applier is primarily indicated for patients undergoing laparoscopic surgical procedures involving dissection and occlusion of blood vessels, ducts and other tubular structures, and for radiographic marking.
TECHNOLOGICAL CHARACTERISTICS:	The ENDO CLIP™ III 5mm Clip Applier is identical to the predicate device in terms of intended use and it operates in a similar manner as the predicate device.
MATERIALS:	All patient contact components of the ENDO CLIP™ III 5mm Clip Applier are comprised of materials which are in accordance with ISO Standard 10993-1.

PERFORMANCE DATA:

In-vitro and in-vivo tests were performed to verify that the ENDO CLIP™ III 5mm Clip Applier was substantially equivalent to the predicate device (K071406) in occluding vessels and other tubular structures and to validate that the ENDO CLIP™ III 5mm Clip Applier performed as intended.

The following describes the testing performed:

- In Vitro Insertion / Removal force
- In Vitro Counter Reliability Test
- In Vitro Firing Force / Clip Formation
- In Vitro Interlocking Break Force
- In Vitro Clip Formation Test
- In Vitro Perpendicular Clip Pulls
- In Vitro Parallel (Axial) Clip Pulls
- In Vitro Jaw Deflection Resistance
  - In Vitro Top Load on Jaw
  - In Vitro Bottom Load on Jaw with wedge plate engaged prior to clip leading
  - In Vitro Bottom Load on Jaw with wedge plate disengaged prior to clip loading
  - In Vitro Side Load on Jaw (Vessel approximated first prior to trigger squeeze)
  - In Vitro Side Load on Jaw (Vessel approximated after wedge plate feed)
  - In Vitro Medial Load on Jaw
- In Vitro Jaw Twist Resistance
- In Vitro Clip next to clip proximity test
- Ex Vivo Burst Evaluation
- Ex Vivo Perpendicular Clip Pull
- Ex Vivo Parallel Clip Pull
- Ex Vivo Clip Twist – Normal Firing (jaw tips vertical to vessel and no underlying tissue)
- Ex Vivo Clip Twist with Shaft Rotation – Normal firing with shaft rotation (jaw tips twisted 90 to vessel and no underlying tissue)
- Ex Vivo Clip Twist – Firing embedded tissue (jaw tips vertical to vessel with underlying tissue)
- In Vivo Hemostasis Evaluation
- In Vivo Jaw Trauma
- In Vivo Blunt Dissection Evaluation
- In Vivo Clip Trauma
- In Vivo Jaw Deflection (Twist) Resistance

Based on the testing data, substantial equivalence has been established.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Covidien
% Ms. Angela Van Arsdale
Regulatory Affairs Product Specialist
60 Middletown Avenue
North Haven, Connecticut 06473

MAY - 3 2012

Re: K121194
Trade/Device Name: ENDO CLIP™ III 5mm Clip Applier
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: FZP, GDO
Dated: April 17, 2012
Received: April 19, 2012

Dear Ms. Arsdale:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121194

Device Name: **ENDO CLIP™ III 5mm Clip Applier**

Indications For Use:

The ENDO CLIP™ III 5mm Clip Applier is primarily indicated for patients undergoing laparoscopic surgical procedures involving dissection and occlusion of blood vessels, ducts and other tubular structures, and for radiographic marking.

Prescription Use ___X____ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K121194